K133984

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JUN 13 2014

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510(k) Summary

Owner's name:	Biodenta Swiss AG
Address:	Tramstrasse 16 9442 Berneck Switzerland
Phone:	+41 71 747 11 11
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Contact person:	Mr. David Eiler, Regulatory Manager
Date summary prepared:	May 14, 2014
Trade / proprietary name:	Biodenta Dental Implant System – Bone Level Tapered D3.0 and L6.5 mm
Common name:	Endosseous dental implant
Device classification name:	implant, endosseous, root-form
Product code:	DZE
Regulation number:	21 CFR 872.3640

Legally marketed device to which equivalence is claimed (predicate device):	
1. Company:	Biodenta Swiss AG
Device name:	Biodenta Dental Implant System - Bone Level D 3.0 to 6.0 mm
510(k) number:	K123512
2. Company:	Biodenta Swiss AG
Device name:	Biodenta Dental Implant System - Bone Level Tapered
510(k) number:	K123415
3. Company:	MIS – Implant Technologies Ltd.

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Device name:	Seven Implants; Biocom Implants; Lance Implants
510(k) number:	K103089

Indications for Use:

Biodenta dental implants are intended for surgical placement in mandibles or maxillae to support single or multiple tooth restorations or terminal or intermediate abutment support for fixed or removable bridgework and to retain overdentures. They are intended for delayed loading.

Device Description:

The Biodenta Dental Implant System – Bone Level Tapered D3.0 and L6.5 mm is an integrated system of endosseous dental implants, which are designed to support prosthetic devices for partially or fully edentulous patients. The system consists of a variety of dental implants, abutments, prosthetic parts and related surgical instruments. The Bone Level Tapered D3.0 and L6.5 mm implants use the same platforms and abutment connections like the Bone Level D 3.0 to 6.0 (K123512). Therefore the abutments and prosthetic parts which are compatible to the Bone Level D 3.0 to 6.0 (K123512) are also compatible to the predicate device.

The submission includes:
- Diameter 3.0 mm Implants with Length of: 10, 12, and 14 mm; Platform B0
- Diameter 4.1, 4.8, and 6,0 mm Implants with Length of: 6.5 mm; Platform B2

Non-clinical Testing Data:

Dynamic fatigue testing was performed with the 3.0 mm diameter implant at room temperature, in air, at 15 Hz to a maximum of 5×10^6 cycles. The test configuration was in conformance with ISO 14801:2007. The fatigue testing result shows that the subject device Biodenta Dental Implant System - Bone Level Tapered D 3.0 and L 6.5 mm is identical to predicate device Biodenta Dental Implant System - Bone Level D 3.0 to 6.0 mm (K123512). Therefore Biodenta Dental Implant System - Bone Level Tapered D 3.0 and L 6.5 mm has sufficient mechanical strength for the intended clinical application.

To compare the implant surface area and bone to implant contact area of the Biodenta Dental Implant System - Bone Level Tapered D 3.0 and L 6.5 mm to the predicate devices, the implants have been remodeled using a CT scanner and generating 3D solid data. The surface area of those 3D models has been calculated for the total implantable length and considering 3mm bone resorption. The Biodenta implant's surface area and bone to implant contact area is larger than the predicate device's surface area and bone to implant contact area. Therefore the surface area and bone to implant contact area is considered to be sufficient.

Clinical Testing:

Non-clinical test data was used to support the decision of safety and effectiveness.

Equivalence to marketed device:

Biodenta Swiss AG demonstrated that, for the purposes of FDA's regulation of medical devices, the Biodenta Dental Implant System - Bone Level Tapered D 3.0 and L 6.5 mm is substantially equivalent to the predicate devices in intended use, material composition, fundamental scientific technology, principles of operation, and basic design.

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Summary Substantial Equivalence Comparison to predicate devices:

	Subject Device	Predicate Devices		
Company	Biodenta Swiss AG	Biodenta Swiss AG	Biodenta Swiss AG	MIS – Implant Technologies Ltd.
Device Name	Biodenta Dental Implant System - Bone Level Tapered D 3.0 and L 6.5 mm	Biodenta Dental Implant System - Bone Level D 3.0 to 6.0 mm	Biodenta Dental Implant System - Bone Level Tapered	Seven Implants; Biocom Implants; Lance Implants
510(k) Number	New device- K133884	K123512	K123415	K103089
Intended Use				
Intended use	Biodenta dental implants are intended for surgical placement in mandibles or maxillae to support single or multiple tooth restorations or terminal or intermediate abutment support for fixed or removable bridgework and to retain overdentures. They are intended for delayed loading.	Biodenta dental implants are intended for surgical placement in mandibles or maxillae to support single or multiple tooth restorations or terminal or intermediate abutment support for fixed or removable bridgework and to retain overdentures.	Biodenta bone level tapered dental implants are intended for surgical placement in mandibles or maxillae to support single or multiple tooth restorations or terminal or intermediate abutment support for fixed or removable bridgework and to retain overdentures.	MIS dental implants are intended to be surgically placed in the bone of the upper or lower jaw arches to provide support for prosthetic devices, such as artificial teeth, in order to restore a patient's chewing function. When a one stage surgical procedure is applied, the implant may be immediately loaded when good primary stability is achieved and the occlusal load is appropriate. MIS short implants are to be used only with straight abutment
Implant Type	Root-form endosseous dental implant Bone Level Implant	Root-form endosseous dental implant Bone Level Implant	Root-form endosseous dental implant Bone Level Implant	Root-form endosseous dental implant Bone Level Implant
Implant Shape	Tapered Wall	Straight Wall	Tapered Wall	Tapered Wall
Implant to Abut. Connection	Internal Hexagon	Internal Hexagon	Internal Hexagon	Internal Hexagon
Implant Diameter (& Length)	D 3.0 mm (L 10 - 14 mm) D 4.1 mm (L 6.5 mm) D 4.8 mm (L 6.5 mm) D 6.0 mm (L 6.5 mm)	D 3.0 mm (L 10 - 14 mm) D 4.1 mm (L 6.5 mm) D 4.8 mm (L 6.5 mm) D 6.0 mm (L 6.5 - 12 mm)	3.5 mm (8 - 14 mm) 4.1 mm (8 - 14 mm) 4.8 mm (8 - 14 mm) 6.0 mm (8 - 12 mm)	D 4.2 (L 6 mm) D 5.0 (L 6 mm) D 6.0 (L 6 mm)
Abutment System	Angled and Straight	Angled and Straight	Angled and Straight	Angled and Straight
Angle	0°, 15°	0°, 15°	0°, 15°	0°, 15°, 20°, 25°
Implant Material	Titanium Grade 4	Titanium Grade 4	Titanium Grade 4	Ti alloy (Ti 6Al 4V)
Abutment Material	Ti alloy (Ti 6Al 4V)	Ti alloy (Ti 6Al 4V)	Ti alloy (Ti 6Al 4V)	Ti alloy (Ti 6Al 4V)
Surface Treatment	Spark Anodization *(same surface modification as K123512 and K123415)*	Spark Anodization	Spark Anodization	Sand blasted and acid etched
Sterilization	Delivered Sterile Gamma Irradiation	Delivered Sterile Gamma Irradiation	Delivered Sterile Gamma Irradiation	Delivered Sterile Gamma Irradiation

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

June13, 2014

Biodenta Swiss AG
Mr. David Eiler
Regulatory Manager
Tramstrasse 16
9442 Berneck
Switzerland

Re: K133884
Trade/Device Name: Biodenta Dental Implant System – Bone Level Tapered D3.0 and L6.5mm
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: II
Product Code: DZE
Dated: May 14, 2014
Received: May 19, 2014

Dear Mr. Eiler:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mary S. Runner -S

Erin I. Keith, M.S.
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K133884

Device Name: Biodenta Dental Implant System - Bone Level Tapered D 3.0 and L 6.5 mm

Indications for Use:

Biodenta dental implants are intended for surgical placement in mandibles or maxillae to support single or multiple tooth restorations or terminal or intermediate abutment support for fixed or removable bridgework and to retain overdentures. They are intended for delayed loading.

Prescription Use __X__ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Sheena A. Green -S
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